

**PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS****Subpart A—General Provisions**

Sec.

- 1271.1 What are the purpose and scope of this part?
- 1271.3 How does FDA define important terms in this part?
- 1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?
- 1271.15 Are there any exceptions from the requirements of this part?
- 1271.20 If my HCT/P's do not meet the criteria in §1271.10, and I do not qualify for any of the exceptions in §1271.15, what regulations apply?

**Subpart B—Procedures for Registration and Listing**

- 1271.21 When do I register, submit an HCT/P list, and submit updates?
- 1271.22 How and where do I register and submit an HCT/P list?
- 1271.25 What information is required for establishment registration and HCT/P listing?
- 1271.26 When must I amend my establishment registration?
- 1271.27 Will FDA assign me a registration number?
- 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

**Subpart C—Donor Eligibility**

- 1271.45 What requirements does this subpart contain?
- 1271.47 What procedures must I establish and maintain?
- 1271.50 How do I determine whether a donor is eligible?
- 1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I maintain?
- 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?
- 1271.65 How do I store an HCT/P from a donor determined to be ineligible, and what uses of the HCT/P are not prohibited?
- 1271.75 How do I screen a donor?
- 1271.80 What are the general requirements for donor testing?
- 1271.85 What donor testing is required for different types of cells and tissues?

- 1271.90 Are there exceptions from the requirement of determining donor eligibility, and what labeling requirements apply?

**Subpart D—Current Good Tissue Practice**

- 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.
- 1271.150 Current good tissue practice requirements.
- 1271.155 Exemptions and alternatives.
- 1271.160 Establishment and maintenance of a quality program.
- 1271.170 Personnel.
- 1271.180 Procedures.
- 1271.190 Facilities.
- 1271.195 Environmental control and monitoring.
- 1271.200 Equipment.
- 1271.210 Supplies and reagents.
- 1271.215 Recovery.
- 1271.220 Processing and process controls.
- 1271.225 Process changes.
- 1271.230 Process validation.
- 1271.250 Labeling controls.
- 1271.260 Storage.
- 1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.
- 1271.270 Records.
- 1271.290 Tracking.
- 1271.320 Complaint file.

**Subpart E—Additional Requirements for Establishments Described in § 1271.10**

- 1271.330 Applicability.
- 1271.350 Reporting.
- 1271.370 Labeling.

**Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10**

- 1271.390 Applicability.
- 1271.400 Inspections.
- 1271.420 HCT/Ps offered for import.
- 1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

EFFECTIVE DATE NOTE: At 69 FR 29829, May 25, 2004, the authority citation to part 1271 was revised effective May 25, 2005. For the convenience of the user, the revised text is set forth as follows:

AUTHORITY: 42 U.S.C. 216, 243, 263a, 264, 271.

SOURCE: 66 FR 5466, Jan. 19, 2001, unless otherwise noted.

**Subpart A—General Provisions****§ 1271.1 What are the purpose and scope of this part?**

- (a) *Purpose.* The purpose of this part, in conjunction with §§207.20(f), 210.1(c),

### § 1271.3

### 21 CFR Ch. I (4–1–05 Edition)

210.2, 807.20(d), and 820.1(a) of this chapter, is to create a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-suitability, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.

(b) *Scope.* (1) If you are an establishment that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act), this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in this part, whether or not the HCT/P enters into interstate commerce. Those HCT/P's that are regulated solely under the authority of section 361 of the PHS Act are described in § 1271.10.

(2) If you are an establishment that manufactures HCT/P's that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, §§ 207.20(f) and 807.20(d) of this chapter require you to register and list your HCT/P's following the procedures in subpart B of this part. Sections 210.1(c), 210.2, 211.1(b), and 820.1(a) of this chapter require you to comply with the donor-suitability procedures in subpart C of this part and the current good tissue practice procedures in subpart D of this part, in addition to all other applicable regulations.

EFFECTIVE DATE NOTE: At 69 FR 29829, May 25, 2004, § 1271.1 was amended by removing the phrase "donor-suitability" and adding in its place the phrase "donor-eligibility" wherever it appeared, effective May 25, 2005.

#### § 1271.3 How does FDA define important terms in this part?

The following definitions apply only to this part:

(a) *Autologous use* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

(b) *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. "Establishment" includes:

(1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cells, tissues, and cellular and tissue-based products; and

(2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products.

(c) *Homologous use* means the replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

(d)(1) *Human cells, tissues, or cellular or tissue-based products (HCT/P's)* means any human tissue derived from a human body and intended for transplantation into another human, as defined under § 1270.3(j). Examples of HCT/P's include, but are not limited to, bone, ligament, skin, and cornea.

(2) *Human cells, tissues, or cellular or tissue-based products (HCT/P's)* means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/P's include, but are not limited to, bone, ligament, skin, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/P's:

(i) Vascularized human organs for transplantation;

(ii) Whole blood or blood components or blood derivative products subject to listing under parts 607 and 207 of this chapter, respectively;

(iii) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;

(iv) Minimally manipulated bone marrow for homologous use and not combined with a drug or a device (except for a sterilizing, preserving, or